JUN - 1 2011

510(k) Summary

MIS Anterior Cervical Plating System

Submitted By:	Life Spine, Inc. 2401 W. Hassell Road, Suite 1535 Hoffman Estates, IL 60169 Telephone: 847-884-6117 Fax: 847-884-6118
510(k) Contact:	Randy Lewis Life Spine, Inc. 2401 W. Hassell Road, Suite 1535 Hoffman Estates, IL 60169 Telephone: 847-884-6117 Fax: 847-884-6118
Date Prepared:	November 19th, 2010
Trade Name:	MIS Anterior Cervical Plating System
Product Code:	CFR 888.3060 - Spinal Intervertebral Body Fixation Orthosis Class II
Classification:	KWQ
Predicate Device:	Nuvasive Helix-Mini ACP (K073275) NEO SL Anterior Cervical Plate (K070285)

Device Description:
The MIS Anterior Cervical Plating System components are temporary implants that are intended for anterior fixation to the cervical spine during the development of a cervical spinal fusion.

The MIS Anterior Cervical Plating System consists of a variety of sizes of plates, screws, and associated instruments. Fixation is provided by bone screws inserted through the plates and into the vertebral body of the cervical spine using an anterior approach.

Intended Use of the Device:

The MIS Anterior Cervical Plating System is intended for anterior fixation to the cervical spine. This system is indicated for use in temporary stabilization of the anterior spine from C2 to T1 during the development of a cervical spinal fusion in patients with:

1. Degenerative disc disease, DDD (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies);
2. Spondylolisthesis
3. Trauma (including fractures or dislocations);
4. Spinal cord stenosis;
5. Deformity or curvatures (i.e. kyphosis, lordosis and/or scoliosis);
6. Tumors;
7. Pseudarthrosis;
8. Failed previous fusions.

Material:

Manufactured from medical grade titanium alloy as described by ASTM F136.

Test Data:

Dynamic Compression as well as Static Compression and Torsion was performed on the MIS Anterior Cervical Plate as described in ASTM 1717, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model. The testing was performed by an independent third party test facility. All mechanical test results are presented in Appendix E.

Testing Conclusions:

The test results demonstrate that the MIS Anterior Cervical Plate is substantially equivalent to the predicate devices, Nuvasive Helix-Mini ACP (K073275) and NEO SL Anterior Cervical Plate (K070285).

Substantial Equivalence:

The MIS Anterior Cervical Plating System is substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 1 2011

Life Spine, Inc.
% Mr. Randy Lewis
2401 West Hassell Road
Suite 1535
Hoffman Estates, Illinois 60169

Re: K103423
Trade/Device Name: MIS Anterior Cervical Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 26, 2011
Received: April 27, 2011

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103423

Device Name: **MIS Anterior Cervical Plating System**

Indications for Use: The MIS Anterior Cervical Plating System is intended for anterior fixation to the cervical spine. This system is indicated for use in temporary stabilization of the anterior spine from C2 to T1 during the development of a cervical spinal fusion in patients with:

1. Degenerative disc disease, DDD (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies);
2. Spondylolisthesis
3. Trauma (including fractures or dislocations);
4. Spinal cord stenosis;
5. Deformity or curvatures (i.e. kyphosis, lordosis and/or scoliosis);
6. Tumors;
7. Pseudarthrosis;
8. Failed previous fusions.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103423